IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Application of Sudhir R. Brahmbhatt	:	
	:	Examiner: Deborah K. Ware
Serial No.: 10/779,828	:	
Filed: February 17, 2004	:	Art Unit: 1651
Title: OXYGEN-ASSISTED FERMENTATION PROCESS	:	
Attorney Docket No.: 22-234	:	

APPEAL BRIEF

Table of Contents

I. Real Party in Interest

The present application is assigned to American Air Liquide, Inc., having an address at 47849 Fremont Boulevard, Fremont, California 94538.

II. Related Appeals and Interferences

The undersigned is aware of no related appeals or interferences.

III. Status of Claims

The pending claims are Claims 1, 3-6, 25, and 26.

Claims 2 and 7-24 have been cancelled.

Claims 1, 3-6, 25, and 26 have been rejected.

Appellants appeal from the final rejection of Claims 1, 3-6, 25, and 26.

IV. Status of Amendments

The following amendments and responses have been submitted in this application:

1) Amendment mailed June 8, 2005, and received by the Office on June 10, 2005;

2) Amendment mailed October 4, 2005, and received by the Office on October 6, 2005;

3) Request for Reconsideration mailed February 10, 2006, and received by the Office on February 13, 2006; and

4) Amendment filed June 14, 2006.

All of the above amendments have been entered.

No amendments have been submitted following the last final rejection, mailed August 28, 2006.

V. Summary of Claimed Subject Matter

The present invention comprises an improved fermentation process, in which a stream of substantially pure oxygen is injected into a fermentation vessel. The oxygen stream is the sole reactive gas, from any source outside the vessel, which is injected into the vessel. The oxygen also is the only gas that is injected continuously into the vessel. The stream of oxygen is moved through the vessel solely due to pressure in an oxygen supply, and not through the influence of a blower or compressor. The oxygen is introduced as a gas, and is not mixed with any liquid before being injected into the vessel.

Fermentation systems are grouped in two categories, namely mechanically-agitated systems, in which there is an impeller, or the like, for mixing the contents of the vessel, and air-lifted systems, which do not use an impeller but instead use bubbles of gas directed through the fermentation medium.

The process of the present invention applies both to mechanically-agitated and air-lifted fermentation systems. All of the independent claims are generic to both kinds of systems.

The following is a more detailed summary of the claimed subject matter, with references to the specification and drawings.

Figure 1 shows the invention used with a mechanically-agitated fermenter. A stream of substantially pure oxygen is injected into a fermentation vessel (page 10, lines 10-11; Figure 1, reference numeral 1). The oxygen supply may comprise stored compressed gas, or it can be continuously generated at the site by an air-separation membrane or pressure swing adsorption system (page 10, lines 14-17). The oxygen could

also be stored as a liquid, in which case it would be vaporized before entering the vessel (page 10, lines 11-14; Figure 1, reference numeral 11).

The stream of pure oxygen is the only reactive gas, from an external source, that is injected into the fermentation vessel (page 8, lines 15-17).

In the case of the mechanically-agitated fermenter, the oxygen is the only gas, external to the fermentation vessel, which is conveyed into the vessel (page 5, lines 6-8).

In the case of an air-lifted fermenter, depicted in Figure 2, a stream of nitrogen, or other inert gas, may be introduced from time to time, in order to remove carbon dioxide and other unwanted fermentation products (page 5, lines 8-11; Figure 2, reference numeral 81). The nitrogen is supplied only when needed (page 16, lines 5-6). That is, nitrogen is introduced periodically (page 15, lines 5-8; page 24, lines 12-14) but not continuously.

Thus, for a mechanically-agitated fermenter, the oxygen is the only gas injected into the fermenter. For an air-lifted fermenter, oxygen is the only gas which is continuously injected, since the nitrogen is injected only occasionally.

Therefore, for both of the above cases, the oxygen stream is the only gas which is injected continuously into the vessel.

The pending claims cover the case in which the invention is practiced as a continuous process (page 18, lines 3-4). The specification teaches that the oxygen may be taken from a compressed gas tank, or by vaporizing liquid oxygen, or by continuously generating oxygen by non-cryogenic means (page 10, lines 10-17). Also, the specification explains that the flow of oxygen is adjusted to control the oxygen concentration in a head space (page 12, lines 1-10). Thus, while the fermentation process is proceeding,

the injection of oxygen is continuous.

The stream of oxygen is moved through the system solely due to pressure in the oxygen supply (page 5, lines 13-15; page 17, lines 16-17). The system uses no blower or compressor to conduct the oxygen (page 5, lines 12-13; page 17, lines 15-16). Also, the injection of oxygen is performed without mixing the oxygen with any liquid (Figures 1 and 2).

The independent claims in this application are Claims 1, 25, and 26.

The following is a concise explanation of the subject matter of Claims 1, 25, and 26, with reference to the specification and drawings.

Claim 1 recites an improvement to a fermentation process, wherein the process includes the steps of placing a fermentation medium in a vessel (page 9, lines 13-14; page 13, lines 3-4; Figure 1, reference numerals 3 and 1; Figure 2, reference numerals 51 and 53), maintaining the fermentation medium in the vessel for a sufficient time to enable a fermentation process to occur in the vessel, and withdrawing a product from the vessel,

the improvement comprising injecting a stream of substantially pure oxygen into the vessel while the fermentation process is occurring (page 10, lines 10-11; page 13, lines 11-18; Figures 1 and 2), wherein the stream of substantially pure oxygen is the sole reactive gas, from any source external to the vessel, that is injected into the vessel (page 8, lines 15-17), and wherein the stream of substantially pure oxygen is the only gas that is injected continuously into the vessel (page 5, lines 6-11), and

wherein the stream of substantially pure oxygen is moved through the vessel solely due to pressure in an oxygen supply (page 5, lines 13-15;

page 17, lines 16-17).

Claim 25 recites a fermentation process, the process including the steps of placing a fermentation medium in a vessel (page 9, lines 13-14; page 13, lines 3-4; Figure 1, reference numerals 3 and 1; Figure 2, reference numerals 51 and 53), maintaining the fermentation medium in the vessel for a sufficient time to enable a fermentation process to occur in the vessel, and withdrawing a product from the vessel,

the improvement comprising injecting a stream of substantially pure oxygen into the vessel while the fermentation process is occurring (page 10, lines 10-11; page 13, lines 11-18; Figures 1 and 2), wherein the stream of substantially pure oxygen is the sole reactive gas, from any source external to the vessel, that is injected into the vessel (page 8, lines 15-17), and wherein the stream of substantially pure oxygen is the only gas that is injected continuously into the vessel (page 5, lines 6-11), and

wherein the injecting step is performed without any blower or compressor (page 5, lines 12-13; page 17, lines 15-16).

Claim 26 recites a fermentation process, the process including the steps of placing a fermentation medium in a vessel (page 9, lines 13-14; page 13, lines 3-4; Figure 1, reference numerals 3 and 1; Figure 2, reference numerals 51 and 53), maintaining the fermentation medium in the vessel for a sufficient time to enable a fermentation process to occur in the vessel, and withdrawing a product from the vessel,

the improvement comprising injecting a stream of substantially pure oxygen into the vessel while the fermentation process is occurring (page 10, lines 10-11; page 13, lines 11-18; Figures 1 and 2), wherein the stream

of substantially pure oxygen is the sole reactive gas, from any source external to the vessel, that is injected into the vessel (page 8, lines 15-17), and wherein the stream of substantially pure oxygen is the only gas that is injected continuously into the vessel (page 5, lines 6-11), and

wherein the injecting step is performed without mixing the oxygen with a liquid (Figures 1 and 2).

The claims contain no "means plus function" language.

VI. Grounds of Rejection to be Reviewed on Appeal

The grounds of rejection to be reviewed on appeal are as follows:

1. Whether Claims 1, 3-6 and 25-26 fail to comply with the written description requirement of 35 U.S.C. §112.

2. Whether Claims 1, 3-6, and 25-26 are unpatentable under 35 U.S.C. §103, over Cheng (A) (US 2003/0080446) or Cheng (B) (US 5798254) or Cheng (C) (US 5985652), in view of EP 341878.

VII. Argument

For purposes of both grounds of rejection, all of the pending claims should be considered together.

A. Summary of Argument

The original disclosure supports the recitation, in the claims, that oxygen is the only gas that is injected continuously into the vessel. The specification describes the process as continuous, and describes the continuous production of a supply of oxygen for use in the process.

The Cheng references all show fermentation processes in which there are two distinct, continuous streams, namely a stream of air and a stream of oxygen. The European reference shows a stream of oxygen, and a separate continuous stream which can be air or an inert gas.

Thus, because both Cheng and the European reference teach injection of two continuous streams, their combination cannot yield a process in which pure oxygen is the only gas continuously injected into the vessel.

Moreover, the Examiner's combination is not even warranted under Section 103, because the Cheng references require two separate oxygen-containing streams to support fermentation. To replace one stream with an inert gas would frustrate the purpose of the Cheng references.

B. All Features of the Claims Are Supported by the Disclosure

In the Amendment filed June 14, 2006, Appellant amended all of the independent claims by adding the limitation "wherein the stream of substantially pure oxygen is the only gas that is injected continuously into the vessel". The Examiner holds that the latter feature is not shown in the original disclosure. The Examiner's holding is incorrect, for the following reasons.

On page 18, line 3, the specification describes the invention as a continuous process.

Since the stream of oxygen is the sole reactive gas injected into the fermentation vessel, a continuous process requires a continuous stream of oxygen. Without oxygen, the fermentation will stop.

The specification states further, at page 10, line 15, that oxygen to operate the fermentation process is "continuously generated" on site.

The term "continuously generated" is used with reference to a non-cryogenic process such as membrane separation or pressure swing adsorption. But the term "continuous" applies equally to oxygen stored as a compressed gas, or vaporized from a liquid. Withdrawing gaseous oxygen from a cylinder would inherently produce a continuous stream. If oxygen is stored as a cryogenic liquid, withdrawing such liquid from its container and vaporizing it, as described at page 10, lines 13-14, would again inherently produce a continuous stream. Thus, all of the methods described in the specification produce a continuous stream of oxygen.

In addition to the above indications of continuous injection, other aspects of the process demonstrate its continuous nature. In particular, the present method includes measurement of the oxygen concentration in the exhaust, the measurement being used to control the flow of fresh oxygen

into the vessel (page 12, lines 12-14). Clearly, the cited passage refers to a continuous process, in which oxygen is continuously supplied.

The Examiner may argue that valve 15, in Figure 1, might be used to shut off the flow of oxygen entirely. But the specification makes clear that the purpose of valve 15 is only to modulate the flow of oxygen, not to shut it off during fermentation. The specification, at page 12, lines 1-10, explains that the valve 15 is used either to increase (page 12, line 7) or reduce (page 12, line 5) the flow of oxygen into the vessel, in response to the measured concentration of oxygen in the exhaust. The specification therefore contemplates a continuous stream of oxygen, injected into the vessel, with the flow rate being increased or decreased in response to the measurement.

The limitation that the oxygen is the only gas that is continuously injected is a logical consequence of the statement on page 5, lines 6-11, and the background given at page 2, line 23 through page 3, line 1. The background passage divides fermentation systems into two types, namely mechanically-agitated systems and air-lifted systems. The passage on page 5 explains that, in the case of the mechanically-agitated fermenter, the oxygen is the only gas injected into the vessel. In the case of the air-lifted fermenter, a stream of nitrogen is periodically introduced for purposes of removal of carbon dioxide. It is thus true, for both cases, that oxygen is the only gas which is continuously injected.

Appellant therefore submits that the limitations added to the claims, in the most recent Amendment, are fully supported by the disclosure as filed, and that the rejection under 35 USC §112 should be reversed.

C. The References, When Combined, Do Not Teach or Suggest the Claimed Invention

The Examiner has rejected all of the claims under 35 USC §103, over a combination of any of the Cheng references, in view of the European reference. The following paragraphs explain the relevant parts of each reference. It is then shown that, even if the references are combined, the result does not yield the claimed invention.

1. Cheng (A)

Cheng (A) (US 2003/0080446) describes a fermentation process in which both air and oxygen are continuously delivered to a fermentation vessel. For example, on page 1, paragraph 0007, Cheng states that the method comprises "injecting air bubbles" and "injecting oxygen bubbles". In paragraph 0008, relating to another embodiment, Cheng repeats the same statement. Later, at page 2, paragraph 0029, Cheng describes air spargers 26 which are distinct from oxygen spargers 22. Cheng further explains that the oxygen bubbles and the air bubbles are mixed (page 3, paragraph 0029). A similar statement appears at paragraph 0030.

In short, Cheng (A) teaches the supply of two distinct, continuous streams of an oxygen-containing gas into a fermentation vessel.

2. Cheng (B)

Cheng (B) describes a process in which two distinct oxygen-containing gases are injected into a fermentation vessel. The abstract makes clear that one of these gases can be air.

In Cheng (B), air is passed upwardly through the fermentation vessel. This step must be continuous; otherwise, the fermentation process would

soon stop. Indeed, the patent describes a process in which the air flows through the system at a rate of 10-400 standard cubic feet/liter-hour (column 3, lines 51-55). Without this continuous flow of air, the process would not operate as intended. Thus, Cheng (B) teaches the use of air to support the normal operation of the fermentation process.

Again, Cheng (B) teaches the supply of two distinct, continuous streams of an oxygen-containing gas into a fermentation vessel.

3. Cheng (C)

Cheng (C) describes another process in which air and oxygen are separately conveyed into a fermentation vessel. Cheng (C) is a division of Cheng (B), and therefore contains essentially the same disclosure.

Thus, Cheng (C) also teaches the continuous injection of both oxygen and air into a fermentation vessel.

4. EP 0341878

European Patent 0341878 shows a fermentation vessel into which "air and/or an inert gas" (page 3, line 38) is injected through pipes 7 or 7a and 9. Oxygen is added, separately, through pipe 13, to a liquid fermentation medium which is withdrawn at opening 15. The liquid is carried by pump 12 back into the vessel.

By using the term "air and/or an inert gas", the European reference implicitly defines the following three cases for the gases injected through pipes 7, 7a, or 9:

1) Injection of air alone;

2) Injection of air and an inert gas; or

3) Injection of an inert gas alone.

Note that, in all three cases, the injection is performed continuously (page 3, lines 38-39).

In Cases 1 and 2, the oxygen injected at pipe 13 would not be the sole reactive gas injected into the vessel.

In Case 3, the oxygen injected at pipe 13 becomes the sole reactive gas injected into the vessel. However, the stream of oxygen is not the only gas injected continuously into the vessel, because the patent explicitly states (page 3, lines 38-39) that the inert gas is supplied continuously.

Now consider the combination of any or all of the Cheng references with the European reference. All of the Cheng references show two continuous streams, one comprising oxygen and the other comprising air. The European reference also shows two continuous streams, one being oxygen (in pipe 13) and the other being air and/or an inert gas (in pipes 7, 7a, 9).

All of the pending independent claims recite that the stream of oxygen is the only gas injected continuously into the vessel. All of the Cheng references, as well as the European reference, show at least two continuous streams.

Thus, even when the references are combined, the result cannot be what is presently claimed. Any combination of the Cheng references with the European reference would still yield a process having two distinct, continuous streams. The present claimed invention requires the use of only one continuous stream.

It is well-settled law that, to establish prima facie obviousness, all

of the limitations of the claims must be taught or suggested by the prior art, In re Royka, 490 F.2d 981, 180 U.S.P.Q. 580 (CCPA 1974), In re Wilson, 424 F.2d 1382, 165 U.S.P.Q. 494 (CCPA 1970). In the present case, when the references are combined, the result still lacks at least one feature recited in all of the claims.

Therefore, for the above reason alone, Appellant submits that the claims are allowable over the references, and that the rejection should be reversed.

D. The Combination Proposed by the Examiner Contradicts the Teaching of the References

In combining the Cheng references with the European reference, the Examiner argues that the air stream in Cheng could be replaced by the inert gas stream of the European reference, under Section 103. The Examiner notes that if such replacement were made, the oxygen in Cheng would become the sole reactive gas, as required by the present claims.

In making this argument, the Examiner has apparently disregarded the limitation that the oxygen be the only gas that is injected continuously into the vessel. In the following paragraphs, Appellant will show that, even if the above limitation were disregarded, the modification proposed by the Examiner would still not be warranted.

The Examiner holds that it would have been "obvious" to replace the air in Cheng with the inert gas of the European reference. The Examiner's statement is wrong, because all of the Cheng references teach the need for two distinct oxygen-containing gases, as explained in more detail in the following paragraphs.

Cheng (B) (US Patent 5798254) teaches the need to use two oxygen-

containing gases in the operation of a fermentation process. See the Summary of the Invention, at column 2, lines 41-43, wherein the patent states that the method comprises:

> utilizing oxygen from both the first oxygen-containing gas and the second oxygen-containing gas to carry out fermentation...

A similar statement appears in Claim 1.

Similarly, Cheng (C) (US Patent 5985652) makes the same statement in the summary of the invention (column 2, lines 43-45). Claim 1 of the patent, which relates to the apparatus, explicitly recites injection of oxygen by both first and second injectors of an oxygen-containing gas.

Cheng (A) (US 2003/0080446) also teaches the injection of two oxygen-containing gases. In the first paragraph of the description of the invention (page 1, paragraph 0014), Cheng explains that air has "traditionally been used as the sole means of providing oxygen to the fermentation process". Cheng goes on to describe a system in which air is no longer the sole source of oxygen, but in which the air is supplemented by a second oxygen-containing gas, namely pure oxygen.

Most importantly, in Claim 12, Cheng characterizes the invention as a method for delivering oxygen-containing fluids to a fermentation vessel. The use of the plural emphasizes what is shown throughout the document, namely a system which provides multiple gases, each containing oxygen.

Thus, all of the Cheng references are based on the need to support the fermentation process with two distinct oxygen-containing streams.

The Examiner now argues that it would be "obvious" to replace the air stream in Cheng with the inert gas of the European reference. But the Cheng references provide no support or justification for such substitution. The Cheng references emphasize the use of distinct streams of oxygen-

containing gases. To replace one such stream with an inert gas would frustrate Cheng's purpose, as one of the streams could no longer support fermentation. Thus, all of the Cheng references teach away from making the proposed modification.

The Examiner may respond that the suggestion for replacing the air of Cheng with an inert gas comes from the European reference. This argument is wrong for two reasons. First, the processes shown in Cheng and in the European reference are very different. Cheng involves the direct bubbling of oxygen and air through a fermentation vessel. The European reference uses the technique of withdrawing liquid from the vessel, adding oxygen to the liquid, and returning the oxygenated liquid to the vessel. These techniques are different, and it makes no practical sense to combine them arbitrarily.

Secondly, the blind replacement of the air of Cheng with the inert gas of the European reference ignores Cheng's teaching that it is desirable to support the fermentation process with two distinct oxygen-containing streams.

The Federal Circuit has held that "[m]odification unwarranted by the disclosure of a reference is improper", Carl Schenck, A.G. v. Nortron Corporation, 218 U.S.P.Q. 698, 702 (Fed. Cir. 1983). See also Illinois Tool Works, Inc. v. Continental Can Co., Inc., 154 U.S.P.Q. 401 (N.D. Ill. 1967), where the court held that the proposed modification of a reference "would be contrary to the purposes of that invention and contrary to the concept and design of the inventor" (Id., at 428).

In the present case, replacement of the air of Cheng with an inert gas would contradict the purpose of the Cheng references, namely to provide two separate oxygen-containing gases. Such a proposed replacement is legally unwarranted under Section 103, as interpreted by the case law.

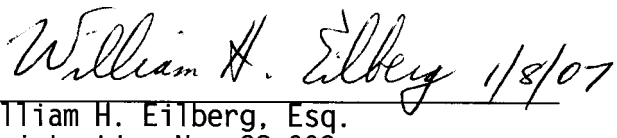
In short, all of the Cheng references teach the need for two separate oxygen-containing gases, enabling oxygen to be supplied to a fermentation vessel from two separate sources. The Examiner's argument that it would be obvious to disregard this clear teaching represents no more than the application of hindsight in an attempt to justify the rejection.

Again, Appellant submits that the Board need not even decide the appropriateness of the Examiner's proposed substitution, because even if the references were combined, the result would not be a process in which oxygen is the only gas continuously injected into the vessel. But even if the above limitation were disregarded, the combination proposed by the Examiner would still be legally unwarranted.

Appellant submits that the Examiner has failed to establish that the claimed invention is obvious. When references are combined, and the result does not contain all of the limitations of the claims, the rejection must be reversed. See Ex parte Sato, 52 U.S.P.Q.2d 1702 (Bd. Pat. App. & Int. 1999).

For the reasons given above, Appellant urges reversal of the Examiner's decision, and requests early allowance of the claims on appeal.

Respectfully submitted,



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VIII. Claims Appendix

The claims on appeal are as follows:

1. In a fermentation process, the process including the steps of placing a fermentation medium in a vessel, maintaining the fermentation medium in the vessel for a sufficient time to enable a fermentation process to occur in the vessel, and withdrawing a product from the vessel,

the improvement comprising injecting a stream of substantially pure oxygen into the vessel while the fermentation process is occurring, wherein the stream of substantially pure oxygen is the sole reactive gas, from any source external to the vessel, that is injected into the vessel, and wherein the stream of substantially pure oxygen is the only gas that is injected continuously into the vessel, and

wherein the stream of substantially pure oxygen is moved through the vessel solely due to pressure in an oxygen supply.

3. The improvement of Claim 1, wherein the process further comprises mechanically agitating the fermentation medium, measuring a concentration of oxygen in an exhaust line extending from the vessel, and adjusting a flow of oxygen into the vessel in response to a measured concentration of oxygen.

4. The improvement of Claim 3, wherein the measuring and adjusting steps are performed substantially continuously.

5. The improvement of Claim 1, wherein the process is performed without mechanical agitation of contents of the vessel, and wherein the

process includes measuring a concentration of oxygen in a head space in the vessel, recycling gas from the head space into the vessel if the concentration of oxygen is greater than a predetermined level, and venting gas from the head space to a region outside the vessel if the concentration of oxygen is less than a predetermined level.

6. The improvement of Claim 5, wherein the measuring step is performed substantially continuously.

25. In a fermentation process, the process including the steps of placing a fermentation medium in a vessel, maintaining the fermentation medium in the vessel for a sufficient time to enable a fermentation process to occur in the vessel, and withdrawing a product from the vessel,

the improvement comprising injecting a stream of substantially pure oxygen into the vessel while the fermentation process is occurring, wherein the stream of substantially pure oxygen is the sole reactive gas, from any source external to the vessel, that is injected into the vessel, and wherein the stream of substantially pure oxygen is the only gas that is injected continuously into the vessel, and

wherein the injecting step is performed without any blower or compressor.

26. In a fermentation process, the process including the steps of placing a fermentation medium in a vessel, maintaining the fermentation medium in the vessel for a sufficient time to enable a fermentation process to occur in the vessel, and withdrawing a product from the vessel,

the improvement comprising injecting a stream of substantially pure oxygen into the vessel while the fermentation process is occurring, wherein

the stream of substantially pure oxygen is the sole reactive gas, from any source external to the vessel, that is injected into the vessel, and wherein the stream of substantially pure oxygen is the only gas that is injected continuously into the vessel, and

wherein the injecting step is performed without mixing the oxygen with a liquid.

IX. Evidence Appendix

There have been no items of evidence submitted in this application, under Rules 130 or 131.

X. Related Proceedings Appendix

The undersigned is aware of no related appeals or interferences.